

**PATENT** 

ATTORNEY DOCKET NO.: STEM1110-4

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Twardzik et al.

Application No.: 10/039,119

Art Unit: 1647

Examiner: To Be Assigned

Filed:

January 4, 2002

Title:

TGF-α POLYPEPTIDES, FUNCTIONAL FRAGMENTS AND METHODS OF

USE THEREFOR

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# TRANSMITTAL SHEET

Sir:

Transmitted herewith for the above-identified application, please find:

- 1. Information Disclosure Statement (2 pages);
- 2. Form PTO-1449 (3 pages);
- 3. Nineteen References;
- Supplementary European Search Report (12 pages); and 4.
- 5. Return postcard.

BEST AVAILABLE COPY

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on May 13, 2004, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-

Karen LePari

In the Application of:

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PATENT Attorney Docket No. STEM1110-4

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement as the items of information contained in this statement were cited in a communication from a foreign patent office in a counterpart foreign application, the communication being dated February 13, 2004, which is not more than three months prior to the filing of this statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: May 13, 2004

Lisa A. Haile, J.D., Ph.D.

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### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97, enclosed are references relating to the aboveidentified application. Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. References cited in a previously filed Information Disclosure Statement on November 21, 2002, in this matter, are not included. For the convenience of the Examiner, the remaining references are listed on the attached Form PTO-1449 and copies are enclosed.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

**CERTIFICATION UNDER 37 CFR §1.8** 

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on May 13, 2004, in an envelope addressed to: Commissioner for Patents, P.O. Box 1459, Alexandria, VA 22313-

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FORM PTO-1449 U.S. Department of Commerce Potent and Trademark Office	STEM1110-4	Serial No.: 10/039,119
1 rademark Office	Applicants: I wardzik et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 4, 2002	Group Art Unit: 1647

## **U.S. PATENT DOCUMENTS**

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
•	DP	4,863,902	09/05/1989	Harunobu Amagase et al.			
	DQ	5,240,912	08/31/1993	George J. Todaro			
-	DR	5,814,308	09/29/1998	Ke Zhang			
	DS	5,942,487	08/24/1999	Takahiro Ogawa et al.			
·	DT	6,486,122 B1	11/26/2002	Daniel R. Twardzik et al.			

#### FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
	DU	WO 95/19785	07/27/1995	PCT			
	DV	WO 98/19712	05/14/1998	PCT			
	DW	WO 99/56785	11/11/1999	PCT			
	DX	WO 00/65028	11/02/2000	PCT			
	DY	WO 03/016480 A2	02/27/03	РСТ			

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. Department of Commerce Patent and Trademark Office	Docket No. STEM1110-4	Serial No.: 10/039,119
MAY	Applicants: Twardzik et al.	
INFORMATION DISCLOSURESTATEMENT BY APPLICANT	Filing Date: January 4, 2002	Group Art Unit: 1647

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

· .	DZ	Cashman, Johanne D. et al, "Mechanisms That Regulate the Cell Cycle Status of Very Primitive Hematopoietic Cells in Long-Term Human Marrow Cultures. I. Stimulatory Role of a Variety of Mesenchymal Cell Activators and Inhibitory Role of TGF-β", Blood, Vol. 75, No. 1, pp. 96-101, 1990.
,	EA	Gandrillon, Olivier et al., "TFG-β cooperates with TFG-α to induce the self-renewal of normal erythrocytic progenitors: evidence for an autocrine mechanism", European Molecular Biology Organization, Vol. 18, No. 10, pp. 2764-2781, 1999.
	ЕВ	Hayman, Michael J. et al., "Self-Renewal and Differentiation of Normal Avian Erythroid Progenitor Cells: Regulatory Roles of the TGFα/c-ErbB and SCF/c-Kit Receptors", Cell, Vol. 74, pp. 157-169, 1993.
1.	EC	Huang, Frederick S. et al., "Role of epidermal growth factor and its receptor in chemotherapy-induced intestinal injury", Am. J. Physiol. Gastrointest Liver Physiol, Vol. 282, pp. G432-G442, 2002.
	ED	Justicia, Carles and Planas, Anna M., "Transforming Growth Factor-α Acting at the Epidermal Growth Factor Receptor Reduces Infarct Volume After Permanent Middle Cerebral Artery Occlusion in Rats", Journal of Cerebral Blood Flow and Metabolism, Vol. 19, pp. 128-132, 1999.
,	EE	Rudinger, J., "Characteristics of the amino acids as components of a peptide hormone sequence", Biological Council, The Co-ordinating Committee for Symposia on Drug Action, pp. 1-7, 1976 (out of print).
	EF	Sharp, Richard et al., "Transforming growth factor α disrupts the normal program of cellular differentiation in the gastric mucosa of transgenic mice", <i>Development</i> , Vol. 121, pp. 149-161, 1995.
<i>9-</i>	EG	Walz, Thomas M., "Transforming Growth Factor-α (TFG-α) in Human Bone Marrow: Demonstration of TFG-α in Erythroblasts and Eosinophilic Precursor Cells and of Epidermal Growth Factor Receptors in Blastlike Cells of Myelomonocytic Origin", <i>Blood</i> , Vol. 85, No. 9, pp. 2385-2392, 1995.

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BY APPLICANT	January 4, 2002	1647

	EH	Yamashita, Hiroshi and Oesterle, Elizabeth, "Induction of cell proliferation in
. ,		mammalian inner-ear sensory epithelia by transforming growth factor α and epidermal growth factor", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 92, pp. 3152—3155,
		1995.

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